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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/378,759	08/23/99	FOX G	06843.0027-0

EXAMINER	
BRANNOCK, M	
ART UNIT	PAPER NUMBER
1646	12

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US PATENT OPERATIONS/RBW
M/S 10-2-E-431
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DATE MAILED: 09/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademark

Office Action Summary

Application No.	Applicant(s)
09/378,759	Fox et al.
Examiner	**Art Unit**
Micha l Brannock, Ph.D.	1646

-- The MAILING DATE of this communication appears on the cov r sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Jul 16, 2001

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 28, 29, 31, and 35-41 is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 28, 29, 31, and 35-41 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☑ Other: NOTICE TO COMPLY WITH SEQUENCE RULES

DETAILED ACTION

Status of Application: Claims and Amendments

1. Applicant is notified that the amendments put forth in Paper 10 7/16/01, have been entered in full.

2. Claims 28, 29, 31, 35-41 are pending. Applicant is notified that the claims will be examined only to the extent that they relate to the elected SEQ ID NO: 11, as per Applicant's election in Paper 9 (7/9/01) and Paper 7 (3/13/01), with traverse, to the restriction requirement of Paper 5 (12/19/01). Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Specification

3. The disclosure is objected to because of the following informalities: Table 4 at page 25 contains several blurred entries: specifically the peptide sequences for HEK 4, 5, and 7 are illegible.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 28, 29, 31, 35-41 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by a specific or otherwise substantial asserted utility. Claims 28, 29, 31, 35-41 are directed antibodies that specifically bind a polypeptide of SEQ ID NO: 11. The instant specification puts forth that the polypeptide of SEQ ID NO: 11 is a member of the Eph-like receptor family (see page 7) and that expression of the polypeptide of SEQ ID NO: 11 is widely distributed in human tissue (page 34). Also, that the polypeptide is useful in a screening method to determine what ligands may activate or inhibit the polypeptide and also to determine what the physiological effects of the polypeptide might be (see page 11). The instant specification puts forth that the claimed "antibodies are useful in the detection of Eph-like receptors in diagnostic assays in the purification of receptor and in the modulation of the Eph-like receptor activation" (see page 11). However, the instant specification does not put forth what, in particular, the antibodies would be used to diagnose nor what particular activity they could be used to modulate. Therefore, these proposed uses lack a specific and substantial utility. These are not specific uses because antibodies to any integral membrane protein could be used in

exactly the same way, i.e. the proposed use is based only on the general properties of membrane proteins and is not specific to the claimed antibodies.

Furthermore, the proposed use of the polypeptide to screen for ligands of the polypeptide or for biologic effects of the polypeptide is not a substantial utility. A substantial utility is a practical use which amounts to more than a starting point for further research and investigation and does not require or constitute carrying out further research to identify or reasonably confirm what the practical use might ultimately be. For example, an assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would be a practical use of the material. However, a method of treating an unspecified disease or condition with a material that has no particular correlation with a disease would not constitute a substantial utility. Basic research, such as studying the properties of the claimed product or the mechanisms in which the product is involved, does not constitute a substantial utility.

The specification puts forth that the antibodies may be useful as a therapy (page 11), yet no particular therapy is set forth. A stated belief that a correlation exists between the polypeptides and any number of diseases is not sufficient guidance to use the claimed antibodies to treat and/or diagnosis a particular disease; it merely defines a starting point for further research and investigation.

The instant application has failed to provide guidance as to how one of skill in the art could use the claimed invention in a way that constitutes a specific or substantial utility. The

proposed uses of the claimed invention are simply starting points for further research and investigation into potential practical uses of the claimed antibodies.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 28, 29, 31, 35-41 are also rejected under 35 U.S.C. § 112 first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 28, 35, 38, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Pasquale EB, Cell Regulation 2(7)523-534, 1991, see Information Disclosure Statement of Paper number 2.

Pasquale disclose polyclonal antibodies that specifically bind Cek5 (see the Abstract). The Cek5 polypeptide is 95% identical to the instant SEQ ID NO: 11, see the attached sequence alignment. Therefore, absent evidence to the contrary, the polyclonal antibodies disclosed by Pasquale are expected to specifically bind to the polypeptide of SEQ ID NO: 11.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (703) 306-5876. The examiner can normally be reached on Mondays through Thursdays from 8:00 a.m. to 5:30 p.m. The examiner can also normally be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB

September 24, 2001

Yvonne Eyler

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600